Maryland Board of Pharmacy
Public Board Meeting
Minutes

Date: November 20, 2013

Name	Title	Present	Absent	Present	Absent
Board Committee					
Bradley-Baker, L.	**Commissioner**	✓		**4**	**1**
Finke, H.	**Commissioner/Secretary**	✓		**5**	**0**
Gavgani, M. Z.	**Commissioner/Treasurer**	✓		**5**	**0**
Israbian-Jamgochian, L.	**Commissioner/President**	✓		**4**	**1**
Jones, David H.	**Commissioner**		✓	**4**	**1**
Robinson, T.	**Commissioner**	✓		**1**	**0**
Rochester, C.	**Commissioner**	✓		**4**	**0**
Roy, S.	**Commissioner**	✓		**4**	**0**
Smith, J.	**Commissioner**	✓		**3**	**2**
St. Cyr, II, Z. W.	**Commissioner**	✓		**5**	**0**
Zagnit, B.	**Commissioner**	✓		**1**	**0**
Board Counsel					
Bethman, L.	**Board Counsel**	✓		**5**	**0**
Felter, B.	**Staff Attorney**	✓		**5**	**0**
Board Staff					
Naesea, L.	**Executive Director**	✓		**4**	**1**
Wu, Y.	**Compliance Manager**	✓		**3**	**2**
Waddell, L.	**Licensing Manager**	✓		**4**	**1**
Gaither, P.	**Administration and Public Support Manager**	✓		**5**	**0**
Jeffers, A.	**Legislation/Regulations Manager**	✓		**5**	**0**
Johnson, J	**MIS Manager**	✓		**5**	**0**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
I. Executive Committee Report(s)	A. L. Israbian-Jamgochian, President	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* 1. L. Israbian-Jamgochian called the Public Meeting to order at 9:45 a.m. 2. L. Israbian-Jamgochian reminded all guests to sign the guest log and to indicate whether they would like continuing education credits. 3. Members of the Board with any conflict of interests relating to any item on the agenda were advised to notify the Board. 4. L. Israbian-Jamgochian reported that all handouts were to be returned by attendees when they leave the meeting. 5. Review and approval of October 16, 2013 public board meeting minutes. October 16, 2013 public board meeting minutes were approved as submitted. 6. L. Israbian-Jamgochain welcomed Lorena de Leon, Administrator, Office of Health Care Quality who presented a brief explanation of the Maryland Background Check Program. Lorena de Leon briefly described the program as highlighted in the PowerPoint presentation which is attached hereto and marked as Attachment No. 1.	Motion by J. Smith to approve the October 16, 2013, public board meeting minutes as presented. Motion was seconded by Z. St. Cyr, II.	Motion was approved.

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II. A. Executive Director's Report	L. Naesea, Executive Director	1. **Operations Updates –** Board of Pharmacy offices will be closed November 27, 28 and 29, 2013 for the Thanksgiving Holiday. Stephen Holmes, the Board's Management Associate will be on sick leave beginning November 26, 2013 due to surgery and will like be out for two or three weeks. Executive Committee has discussed trying to immediately acquire 3 temporary positions previously to support the Compliance Unit between now and January. 2. **Meeting Updates** - L. Naesea and Commissioner H. Finke attended the NABP District 1 and 2 annual meeting in Bar Harbour, Maine on October 17 through 19, 2013. H. Finke reported on three resolutions that were adopted at this meeting. These resolutions are attached hereto as "Attachment No. 2." **3. Audit Findings** - L. Naesea reported that as a result of the Legislative Audit the Board received "draft" notes of 3 findings that the Board will be responding to at a meeting to be held Friday, November 22, 2013. L. Naesea stated that all three of these Legislative findings were all issues that arose as a result of the implementation of the Board's new MIS system. The first finding stated that the Board did not always deposit cash receipts in a timely manner. The Board concurred with the first legislative finding and responded to this finding that procedures have been implemented to assure this does not happen in the future. The second finding was that the Board did pursue or collect bank charge backs (bounced checks). The issues concerning this finding have been resolved but it was noted that the Board may need additional staff to timely pursue future bank charge backs. The third and final finding was that the Board had not documented that a license was issued for every dollar received. J. Johnson, the Board's MIS Manager is working to develop the reports necessary to satisfy this legislative finding. The Board may have to ask	Motion by M. Gavgani to request expedited staffing for the Compliance Unit. Motion was seconded by D. Jones.	Motion was approved

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		the Board's vendor, Systems Automation, to reconfigure the MLO system to address this finding. **4. Pharmacy Interns -** L. Naesea welcomed the Board's two interns, Sharon Hu from the University of Maryland at Baltimore School of Pharmacy and Ethel Fomundam from the University of Maryland Eastern Shore School of Pharmacy who begin their internship at the Board on November 12, 2013 and will continue at the Board for five weeks.		
B. Administration & Public Support	P. Gaither, Admin.& Public Support Manager	**Personnel Updates** – The Board has hired five temporary employees related to processing for its scanning project. The Board has submitted a budget deficit for four sterile compounding positions. Two pharmacists to inspect sterile compounding sites, one laboratory specialist to analyze reports and an administrative staff person to meet the anticipated increase in applications and mail processing. The Board's 2015 budget also requested a pharmacist deputy, to support the Executive Director, two administrative specialists, two health occupations investigators, one temporary office services clerk and one temporary web design employee. In addition the Board will be submitting an amendment to its 2014 budget request to include temporary administrative positionsthe Compliance Unit. **Contract Updates –** The scanning contract has undergone three revisions due to OPASS revising its contract template. Discussions are ongoing and the Board hopes to have this matter officially approved as soon as the contract goes before the Department of Public Works (DPW). DPW must approve this contract as the contract amount is over $200,000.00**.** P. Gaither reported that she will be meeting with L. Naesea and Commissioners J. Smith and H. Finke to review the Board's contract with PEAC in preparation for next year's contract. At present this contract is a "sole source" contract.		

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C. Management Information **Sy**stems	John Johnson, MIS Manager	• MIS Manager John Johnson reported that he and L. Naesea met with the MIS Steering Committee, headed by Commissioner M. Gavgani. The committee is comfortable moving forward with the next round of enhancement/configurations for online renewals to include Pharmacy and Pharmacy Waiver renewals, and Sterile Compound configurations. • The MIS Steering Committee also approved the Board's MIS Unit to develop a standard form for the Board's units to submit any desired MLO system enhancements. • J. Johnson reported that he is developing a scope of work for P. Gaither to include in an RFP for a vendor to develop/install inspection software for use by Board compliance inspectors.		
D. Licensing	L. Waddell, Licensing Manager	Monthly Statistics for October, 2013. Pharmacists: • New Applications – 63 • Renewals – 406 • Total Licensed – 9764 Pharmacists Administer Vaccinations: • New Applications – 62 • Renewals – 29 • Total Certified - 3467 Technicians: • New Applications – 106 • Renewals – 333 • Total Registered –8596 Student Technicians • New Applications – 27 • Renewals – 231 • Total Registered – 913		

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		Pharmacies: • New Applications – 28 • Renewals – 0 • Total Pharmacies- 2005 Distributors: • New Applications – 22 • Renewals – 9 Total – 927		
E. Compliance	Y. Wu, Compliance Manager	1. Monthly Statistics for October, 2013 <u>Complaints & Investigations</u>: New Complaints- 20 Resolved (Including Carryover) –46 Final disciplinary actions taken – 18 Reversal – 0 Summary Actions Taken –0 <u>Inspections:</u> 133 Annual Inspections- 114 Opening Inspections- 11 Closing Inspections - 0 Relocation Inspections- 1 Board Special Investigation Inspections – 7 Division of Drug Control Closing Inspections: 0		
	Y. Wu, Compliance Manager reporting for PEAC	• Total Pharmacist Rehabilitation Committee Clients – 17 • Pharmacist Clients – 15 • Technician Clients – 1 • Pharmacy Student Clients – 0 • Clients Monitored by Board Req. PEAC Assistance – 1		

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		• Drug Testing Results – 19 • Number of Positive Results – 0 • Discharged Clients/Closed Cases – 2		
F. Legislation & Regulations	A. Jeffers, Legislation & Regulations Manager	**REGULATIONS: (5 Open Chapters)** **10.34.19 Sterile Pharmaceutical Compounding** with **10.34.09 Fees** **Informal comments:** **Sterile Compounding Regulations 11.07.2013 MSHP Response Final** **10-24-13etter to Anna D. Jeffers.Finaldoc Doherty** **Ch_397_hb0986T Pharm Cpdg Acc Bd 101613** **Comment 10 34 19 Sterile Drug Prod Waiver 101513 St. Agnes** **Comment 10 34 19 Sterile Drug Prod Waiver 102413 Krug** **DHMH Draft Comments on Sterile Drug Products and Waiver** **Draft 10 34 19 Sterile Drug Prod and Waiver 101113 Pharm Cpdg Accred Bd** **Draft 10 34 19 Sterile Drug Prod Waiver 101113 DTaylor** **Mel Rubin - MASA comment 103013** **Proposed Md Cmpdg Regs - JCB Laboratories 110813** **Question 10.34.19 Sam Georgiou 101713** **Sterile Compounding Regs - Informal Comments 10-25-13 MHA** **waiver_varianceapp2 JCB Labs**		

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		Board approval requested for the following Board response: **Draft Board Response to Informal Comments 111513** **The Board approved the following response to the informal comments received with the condition that the Sterile Compounding Subcommittee would meet on November 21st to make revisions as necessary:** Thank you for providing informal comments regarding draft revisions to COMAR 10.34.19 Sterile Compounding ***Preparations and Sterile Drug Products***. The revisions were made to COMAR 10.34.19 as mandated by HB 986 State Board of Pharmacy – Sterile Compounding – Permits, Chapter 397, 2013, (HB986). The draft proposed regulations released for informal comment have been incorporated into one proposal with the following renumbering of the regulations: .17 Sterile Compounding Permit Application Requirements. .18 Minimum Requirements for Inspections of Sterile Compounding Permit Holders. .19 Reporting Requirements for Sterile Compounding Permit Holders. .20 Sterile Drug Products. .21 Sterile Drug Product Waiver. This letter will address all the informal comments received from stakeholders in one letter including a description of revisions as a result of those comments. The letter is organized by regulation number with a section on "General Comments" at the end. **.01 Scope.** At the end of Section B. the word "***and***" had been inadvertently added and the Board has removed it. **.03 Definitions.** "Adverse Event" It was suggested that this definition be revised to read "Adverse events" means: (a) Any adverse patient outcome related to the ***sterility of the sterile*** compounding process. The Board considered this wording, but determined that only adding the word "***sterile***" would be sufficient so as not to place limits on	**Responses Approved**	

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		what would be considered an adverse event. It was noted in "(b) Evidence of environmental contamination, including microbial contamination above the threshold as set forth in USP 797 Standards." that USP 797 would consider a facility contaminated even below the threshold if the bacteria are pathogenic. The Board responds that there is currently a threshold in USP 797 Standards for pathogenic bacteria and no revisions will be made. "Biological safety cabinet" It was suggested that the Board include two types of biological safety cabinets in the definition. The Board, to be consistent with USP 797 Standards, will be making no revisions to this definition. "Clean room" It was noted that this definition did not take into consideration that some "open architecture" clean rooms consist of only an ISO-5 environment, therefore; the Board added "***a room with an ISO-5 environment or"*** to the beginning of the definition. "Compounding" It was suggested to remove the word "assembling" from the definition of "compounding." The Board determined that the word "assembling" is necessary in the definition since "assembling" does occur in some locations and it is also included in the definition set forth in the law. See Health Occupations Article, 12-101, Annotated Code of Maryland. "Designee" It was suggested that the Board consider adding standards for the Board's approval of a "designee." The Board decided to add a phrase "***trained in USP 797 Standards and/or FDA good manufacturing practices***" after "public agency or private entity" so that it would be clear that any designee would be properly trained to inspect sterile compounding facilities. "Health Care Practitioner" It was asked if dentists, podiatrists, and veterinarians are currently allowed to compound drugs. The Board defers to the licensing boards of these health professions, but the Board's understanding is that it is within these professions' scope of practice. See Health Occupations Article, 12-102, Annotated Code of Maryland, that allows		

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		these individuals to personally prepare prescriptions. "Low risk," "Medium risk," and "High risk" were removed from the proposal since those terms are duplicative of the definition of risk level which references USP 797 "Sterile compounding facility" The definition of "sterile compounding facility" was revised to clarify the environment where sterile compounding would be performed and where sterile compounding permits are required. *(16-2) "Sterile compounding facility" means a pharmacy, a health care practitioner's office, or any other setting in which sterile compounding is performed* ***in a controlled environment as required by USP 797 Standards.*** "Sterile drug product" It was noted that generally the word "product" refers to a manufactured drug. In the HB986, however; it is included in the definition of "sterile drug product" and the Board is bound by the definition in the statute. Please note that the definitions have been renumbered for clarity. **.09 Minimum Facility Requirements.** At the beginning of Regulation .09, under A. Controlled Environment, the regulations require that a sterile compounding facility have a controlled environment. Concern was expressed that this would require the same facility and supply requirements for a pharmacy as "immediate use" compounding on a nursing unit or operating room in a hospital. It was suggested that there be an exemption in these regulations for "immediate use." The Board will not be adding an exemption because USP 797 Standards already include an exemption for "immediate use." The Board will, however; add to the end of the first subsection the following for clarification purposes: (1) The [pharmacy] sterile compounding facility shall have a controlled environment that meets USP 797 Standards. B. and C. Controlled Environment – Clean Room and Antiroom		

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		It was suggested to clarify regarding the barrier isolator exemption. The Board will not be adding clarification here as it is addressed in USP 797 Standards. **.17 Sterile Compounding Permit Application Requirements. (.19 in the released draft)** In Section D(7) the applicant is required to "submit reports and corrective actions taken or proposed in response to adverse events identified 12 months before submission of the application;" A comment was received that asked whether this would be required for renewal since it would be duplicative. The Board will not be asking for these reports upon renewal. See Section H for the renewal requirements. Section F states: "A separate sterile compounding permit is required for each site at which sterile compounding is performed." Clarification has been requested regarding the scope of practitioners and physical plant covered under a single permit. There was concern that nursing units, hospital clinics, physician's offices and pharmacies would be required to obtain this permit if sterile compounding. It is the Board's understanding that nursing units do not perform sterile compounding, except perhaps for immediate use. Immediate use is an USP 797 Standards exemption. If a person is compounding in a controlled environment, then a sterile compounding permit would be required. **.18 Minimum Requirements for Inspections of Sterile Compounding Permit Holders. (.20 in the released draft)** It was recommended to revise subsection B(3) to be consistent with USP 797 Standards so that it would read: "The sterile compounding permit holder shall provide as a part of the inspection process: (3) Microbial testing of a sampling of the sterile compounded preparations of the sterile compounding facility ***if applicable according to USP 797 Standards***." The Board agrees with this revision since there may be circumstances when sampling tests would not be available for inspection. This would occur because testing the preparation might compromise the preparation's integrity for a specified patient. **.19 Reporting Requirements for Sterile Compounding Permit Holders. (.21 in the released draft)** It was suggested that reporting adverse events including corrective actions taken or proposed should be reported within 15 business days after sampling results are conclusive, instead of 5 days as required by the proposed regulations. Even		

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		though some sampling results may take longer than 5 days, the Board would like whatever information a permit holder has as soon as possible within the 5 day timeframe. The permit holder can send further results as they become available, but the Board wants to know if there is a problem as soon as the permit holder knows. Additionally, it was suggested that reporting of deficiencies also be extended to 15 business days. The Board does not agree, and again, wants to know of deficiencies as soon as possible within the 5 day timeframe. The Board made a revision for clarification to Section B(2) to clarify that deficiencies would be related to the sterile compounding process: "B. Report to the Board within 5 calendar days: (2) Deficiencies ***related to the sterile compounding process***." **.20 Sterile Drug Products. (.17 in the released draft)** This section, taken directly from HB986, sets forth the requirements for persons that are preparing and distributing sterile drug products. Those persons require an U.S. Food and Drug Administration (FDA) manufacturer's permit and a Wholesale Distributor Permit from the Board. Those persons who prepare sterile drug products would not be required to have a sterile compounding permit. The only revision that the Board will make to this section concerns the requirement that a person that prepares and distributes sterile drug products shall hold a wholesale distributor's permit, ***if applicable***. This was added to accommodate the practice of intracompany transfers of sterile drug products, which would not require a wholesale distributor permit. This often occurs within health systems. Keep in mind that a hospital that prepares patient specific sterile compounded medications would require a Sterile Compounding Permit and would not fall under this section. **.21 Sterile Drug Product Waiver. (.18 in the released draft)** In the proposed Section A(1) it specifies that the Board may issue a waiver to a person that prepares and distributes sterile drug products only for a specified sterile drug product. A comment was received that asked the Board to consider granting a waiver for compounding pharmacies that covered all the medications compounded within that pharmacy if the pharmacy were able to meet all of the requirements of the Board, including the new Sterile Compounding Permit requirements. The Board is not able to make this change since the law specifies		

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		that waivers may be granted only for a specified drug product. In the proposed Section A(1)(a)(i) it lists criteria for exigent circumstances. One of those criteria is that the sterile drug product is listed on the current drug shortages index by the FDA. It was suggested that there might be timelier or more accurate sources for drug shortage information. To allow for other sources the Board revised this section by adding: "***or other nationally recognized index;***" In the proposed Section A(1)(a)(ii) one of the criteria for exigent circumstances is that the specified drug product must only be prepared and distributed by the applicant or the person applying for the waiver. It was questioned in one of the comments whether this may restrict who may apply to compound a specific medication on the drug shortage list. The language in this section does not restrict who may apply. It only requires that whoever is applying must do the actual preparation and distribution. Additionally, a comment was received that questioned who was meant by "person applying for the waiver." Person in this context would be the facility applying to perform the compounding of a sterile drug product, not the individual completing the application. In the proposed Section A(2)(a) it lists the health care providers in the State who will assist the Board in determining clinical need for a waiver. A comment was received that questioned why the Board has limited the stakeholder feedback to licensed health care providers from specified trade associations. Upon consideration, the Board agrees and revised this section to read: "***For which there is a clinical need as determined by the Board with input from relevant professionals as determined by the Board;***" In the proposed Section A(2)(b) "clinical need" may not be based on financial or business concerns. A comment was received requesting that clinical need may not *primarily* be based on financial or business concerns since there may be situations where a financial concern may be one component of a need. The Board will not be adding a financial component to criteria for clinical need as these concerns do not fit within a patient's exigent circumstances or a patient's clinical need for a medication.		

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		In the proposed Section A(3)(b) the applicant is required to meet requirements such as identifying "in the application the highest USP 797 risk levels of compounding engaged in by the applicant." A comment was received that suggested that if the facility is FDA registered, the FDA may require good manufacturing practice compliance rather than USP compliance. The Board notes that an applicant applying for a waiver would apply because that applicant does not have an FDA permit. Additionally, another comment was received about this section with concerns that only one level of risk would be reported. The Board notes that it would only need to know the highest risk level of preparation. If an applicant meets the standards for a high risk level than the applicant would also meet lower risk levels as well. In the proposed Section A(3)(g), it was noted by more than one individual, that the word "If" was missing from the beginning of this sentence. The Board has added it in. In the proposed Section A(3)(h), the applicant is required to submit evidence of good standing with any other Maryland licensing entity or the licensing entity in the state in which the applicant is located. It was asked if the Board should also require evidence of good standing from the FDA. Again, if the applicant is applying for a sterile drug product waiver, it would not have an FDA permit. In the proposed Section H, the holder of a sterile drug product waiver shall submit amendments to the waiver in advance to the Board for approval, including the addition of a specified sterile drug product. Concern was expressed that in cases when a patient's need is urgent, an exception to this requirement may be warranted. The Board assures the public that it will give urgent patient needs priority when approving sterile drug product waivers or amendments to sterile drug product waivers. Please note that renumbering has occurred in the final proposal. **General Comments** Please be advised that the law in Maryland is clear. Health Occupations Article, 12-101, Annotated Code of Maryland. "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug or device:		

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		(i) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient/pharmacist relationship in the course of professional practice; or (ii) For the purpose of, or incident to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device. (2) "Compounding" includes the preparation of drugs or devices in anticipation of a prescription drug order based on routine, regularly observed prescribing patterns. This does not allow a practitioner to write drug orders for office use or allow a pharmacy to compound a sterile product for use in an office. There was some confusion expressed in one comment about what is meant by "distribute," "distribution," and "dispense" within HB986. HB986 requires a practice to acquire a Sterile Compounding Permit regardless of whether the medication is "administered," "dispensed," or "distributed." The legislation is about sterile compounding of a product. Non-sterile compounding, such as amalgam filling in the restoration of a tooth, is not regulated by this legislation. A few of the informal comments pointed out formatting and grammatical errors in the proposed regulations. The Board made corrections and revisions where necessary. Thank you again for your thorough consideration of the release of draft regulations to implement HB 986 State Board of Pharmacy - Sterile Compounding - Permits, for sterile drug products and the waiver of requirements as allowed under HB 986 and of the separate release for sterile compounding permit requirements. The Board approved the revisions set forth above at its November 20, 2013 Public Board Meeting. The final revisions are attached. Please monitor the Maryland Register for the initial publication of the proposed revisions to COMAR 10.34.19 Sterile Pharmaceutical Compounding. http://www.dsd.state.md.us/MDRegister/mdregister.aspx A 30 day comment period will follow. **Board approval requested for all the proposed revisions.**		

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		Proposed COMAR 10.34.19 Sterile Compounding Preparations and Sterile Drug Products **The Board approved the proposal with the condition that the Sterile Compounding Subcommittee, meeting on November 21, 2013, would make final revisions as necessary.** **10.34.22 Licensing of Wholesale Prescription Drug or Device Distributors** **Board approval requested** for revisions to this proposal that provide the Division of Drug Control with certain information and notification of closing of a wholesale distributor. **10.34.22 and 10.34.37 to_16567_1 For 112013 Bd Mtg** **The Board approved the proposed revisions with the following final version of what a wholesale distributor would provide to the Division of Drug Control when closing:** *(6) At the closing inspection, the wholesale distributor shall provide to the Division of Drug Control the following pertaining to controlled dangerous substances:* *(a) The exact date on which the wholesale distributor ceased to operate;* *(b) A copy of the closing inventory of controlled dangerous substances required by the Drug Enforcement Administration.* *(c) The names, addresses, telephone numbers, Drug Enforcement Administration registration numbers, Division of Drug Control registration numbers, and Board permit numbers, if applicable, of the persons or business entities to whom controlled dangerous substances in stock were returned or transferred under this regulation; and* *(d) The State Department of Health and Mental Hygiene Controlled Dangerous Substance Registration for cancellation.* **10.34.32 Pharmacist Administration of Vaccinations** Board approved proposal with a revisions to Regulation .08 Fees, on 092013. Submitted 092013 to DHMH Emergency for sign off and publication. Board of Nursing had concerns about the possible fees that could be charged to Medicaid recipients and suggested to leave the reimbursement rate for the administration of vaccinations stand for Medicaid reimbursed vaccinations and allow the maximum rate for all other vaccinations. The Practice Committee	**Approved.**	

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		agreed and informed BoN that under the law no additional fees may be charged for vaccinations administered to Medicaid patients, so there would be no need to adjust the revisions to COMAR 10.34.32.08 Fees. **10.34.33 Prescription Drug Repository Program** Proposal to be revised pursuant to federal regulations. **10.13.01 Dispensing of Prescription Drugs by a Licensee** The Board previously revised the proposal so that if a dispensing permit holder has more than one dispensing site, the DDC may not inspect the same site twice within the 5 year permit period. The Practice Committee recommended revising the proposal to require inspections of more than one dispensing site upon renewal. **Board approval requested for:** **Draft Proposal 10.13.01 102313 Practice Recommendation** **The Board approved additional revisions regarding inspections as noted below. The Board requested that these revisions be sent to stakeholders before submission into the promulgation process.** *C. The Division of Drug Control shall:* *(1) Enter and inspect the practice location**[s]** of a licensee who holds an initial dispensing permit:* *(a) Within 6 months after receiving the annual report set forth in §A(1) of this regulation; and* *(b) At least one more time during the duration of the permit;* ***(2) If a licensee who holds an initial dispensing permit has more***	**Approved.**	

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		than one practice location: ***(a) Enter and inspect a random practice location of the licensee within 6 months after receiving the annual report set forth in §A(1) of this regulation; and*** ***(b) Enter and inspect a different practice location at least one time during the duration of the permit;*** ***(3) If a licensee who holds a dispensing permit is seeking renewal:*** ***(a) Enter and inspect random practice locations of a licensee within 6 months after receiving the annual report set forth in §A(1) of this regulation; and*** ***(b) Enter and inspect a different practice location at least one time during the duration of the permit; and*** ***(4)*** *Enter and inspect the practice locations of a licensee who holds a renewed dispensing permit at least two times during the duration of the permit****;***		

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		(5) If the Division of Drug Control finds a deficiency at one practice location, enter and inspect all practice locations of the licensee who holds a dispensing permit; ***(6) Report to the Board of Pharmacy a wholesale distributor not licensed in Maryland;*** *(7) Report the results of the inspections required under §C(1) and (2) of this regulation to the respective board of licensure; and* ***(8) Report deficiencies noted in the inspection report to the Board of Pharmacy.*** **MEETINGS:** **1) Workgroup on Pharmacy Benefits Managers and Specialty Drugs - October 29, 2013.** The following groups presented at the October 29th Meeting: • PBM Panel including Express Scripts and CVS Caremark • League of Life and Health Insurers • Medicaid MCO Survey presented by Marie Grant of DHMH • Maryland Insurance Administration **NEXT STEPS:** At the end of the meeting, Chairman Hammen asked everyone to review the new Delaware law regarding PBMs and specialty drugs. He would like stakeholders to comment on the Delaware law and what stakeholders would like to see in legislation for the 2014 legislative session.		

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		DE Specialty Drugs **Draft Board comment to HGO – PBMs and Specialty Drugs** **The Board approved submitting the following comment to Chairman Hammen. Revisions at the Board meeting included adding "patient choice" and information about the National Association of Boards of Pharmacy Task Force to Examine Regulation of Pharmacy Benefit Managers.** Dear Chairman Hammen: The Maryland Board of Pharmacy (the "Board") submits this comment and recommendation regarding the dispensing of specialty drugs to Maryland patients. **Background.** At the present time each health insurance company determines their own unique list of specialty drugs for its beneficiaries. There is no standardization, consistency, or uniformity in designating "specialty drugs." This has resulted in: • Pharmacists being required to handle drugs in one manner for one insurance plan and differently for a second plan; • Delays in prescriptions being filled for patients with immediate need even if a pharmacy has a contract with a Pharmacy Benefit Manager (PBM); • Delays in prescriptions being filled for patients with immediate need when the PBM mandates the use of mail order; and • Patients denied freedom of choice of pharmacy. Ultimately, this has resulted in inconsistent pharmacy patient care based on the health insurance plan and restricted access to pharmacy patients of the medications they need. **Delaware Law** The Board has reviewed the legislation passed in Delaware, SB 35, Chapter 133, 2014, and would be able to support similar legislation. The definition of "specialty drug" set forth in the bill is comprehensive and addresses the attributes that make specialty drugs unique. The Board's one concern is the cost threshold that the total monthly cost of the prescription is $600 or more. The Board	**Approved.**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		believes that specialty drugs should not be based on costs; rather the uniqueness of the drug and the special education, counseling and monitoring that is involved. The Board does support that the Delaware legislation prevents a health plan or other entity from requiring specialty drugs be obtained through a designated pharmacy or other source of drugs. This is in line with the Board's position and policies in the past that patients should have nonrestrictive access to their prescription medications, utilizing a pharmacy of their choice. Pharmacists all receive similar training and any pharmacist licensed in Maryland has the ability to dispense, educate and counsel patients as to appropriate use of any prescription drug. Allowing patients to obtain specialty drugs from a pharmacy of their choice would not diminish the care that they would receive. Indeed, utilizing a pharmacy that has been dispensing to a patient over a period of years, sometimes decades, provides continuity of care that cannot be matched. If a particular medication is so unique as to require specialized training, pharmacists would seek out that training so as to provide the best standard of care. The Board also suggests that any specialty drug legislation in Maryland address the limited distribution of specialty drugs by wholesale distributors. At the present time, many wholesale distributors will only distribute drugs designated by PBMs as specialty drugs to certain pharmacies resulting in some pharmacies being unable to obtain these drugs. For your information the National Association of Boards of Pharmacy (NABP) announced, in its October 2013 Newsletter, that it will convene a Task Force to Examine Regulation of Pharmacy Benefit Managers on October 22-23, 2013. A report from the Task Force will be available once approved by the NABP Executive Committee. The Board would like to take this opportunity to thank you and your staff for the time and effort expended to address this issue through several workgroup meetings pulling the various stakeholders together. The Board believes this is an important issue for discussion and legislation. Should you have questions or additional concerns, please feel free to contact Anna D. Jeffers, Legislation and Regulations Manager at (410) 764-4794. After he reviews all comments, he may circulate a proposed bill for 2014 for		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		comment. 2) **Maryland Ambulatory Surgery Association – October 30, 2013** Presented with Mel Rubin explaining HB 986. **HB 986 MASA Presentation ADJ** Anna included the presentation as an FYI. **3) Naturopath Briefing in Annapolis, November 12, 2013.** Ethel Fomundam, intern, reported on the briefing. It appears that many issues have been resolved and a bill will be introduced in the 2014 Legislative Session. 4) **Meeting with Senator Joan Carter Conway - November 14, 2013** regarding legislative initiative for the 2014 Legislative Session. The Board's three legislative initiatives for 2014 were discussed with Senator Carter Conway. She is supportive of the legislation and will sponsor the intern registration legislation and consumer member serving on the executive committee legislation. She will discuss with Chairman Hammen and the Secretary regarding the 10 mile radius restriction and will float the bill in 2014. 4) **Immunet Registry Study Workgroup - November 15, 2013** DHMH is studying the feasibility and desirability of requiring all Maryland healthcare providers who administer vaccinations to report those vaccinations to ImmuNet, the Maryland immunization registry, and would like the Board's input on these issues. Anna Jeffers, and both interns, attended the first meeting. **ImmuNet Summary with Questions_Nov 2013** **ImmuNet Work Group Meeting_Nov 15 2013** **ImmuNet Workgroup Meeting Agenda_Nov 15 2013** Sharon Hu, intern, reported in the Immunet Registry Study Workgroup. **OTHER MATTERS:** **1) Legislative Reports:** **Board approval requested for:**		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		a) Prescription Drug Repository Annual Report **DRAFT RxDrugRepReport to GenAssembly 100913** **Board approved.** **b) Wholesale Distributor Annual Report** **DRAFT Report WholesaleDist Program 101313** **Board approved.** **c) Report on the Implementation of Sterile Compounding Permits and Sterile Drug Product Waivers** **Draft Report HB 986 Sterile Comp 102913** **Board approved.** **2) Re: Draft legislative proposal - mandated child abuse reporter training** **Draft Board Response – mandated child abuse reporter training** **The Board approved sending the following letter to Senator Shank:** Dear Senator Shank: The Maryland Board of Pharmacy (the "Board") has received a copy of your proposed draft legislation that would mandate a 90 minute continuing education course on recognizing and reporting child abuse, child sexual abuse, and neglect before initial licensure by a health occupation board and every 3 years for renewal. The proposal as drafted would apply to licensees, applicants for licensure and unlicensed practitioners, such as students, who work directly with patients. The Board's mission is to protect Maryland consumers and to promote quality healthcare in the field of pharmacy through licensing pharmacists and registering pharmacy technicians, issuing permits to pharmacies and distributors, setting pharmacy practice standards and through developing and enforcing regulations and legislation, resolving complaints, and educating the public. As of April 1,	**Approved.** **Approved** **Approved.** **Approved.**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		2014, the Board will begin issuing sterile compounding permits and accepting applications for sterile drug product waivers. Wholesale distributors and their employees, by law, may not dispense to patients or consumers. See Health Occupations Article, 12-6C-01(u), Annotated Code of Maryland. Your draft legislation appears to allow for a waiver for licensees such as wholesale distributors. Proposed Health Occupations Article, 1-222(A)(3). The Board supports this waiver. The Board appreciates the need for licensees to recognize and report child abuse, child sexual abuse and neglect. Pharmacists are positioned in many settings to assist with monitoring children who may be at risk of neglect/abuse. In fact, legislation effected in 2013 allows community pharmacists to immunize children as young as age 9 for influenza and as young as age 11 with a prescription for immunizations that are listed in the Centers for Disease Control and Prevention's recommended immunization schedule. Many pharmacists also interact with patients of all ages through counseling and patient education concerning the medications they are dispensed. Thus, most pharmacists have daily opportunities to identify possible neglect and abuse and take steps to intercede. Unfortunately, continuing education courses regarding this topic are not routinely available for the pharmacy community. Courses that address issues about awareness and how to report child neglect/abuse are offered for students in pharmacy schools, but are only periodically available through a few pharmacy associations post-graduation. Thus, the Board feels that the goal of educating pharmacy professionals about this important issue may be better met through ongoing newsletter articles developed in collaboration with professional associations, the Maryland Pharmacy coalition, and Maryland's pharmacy schools. Awareness of child abuse, child sexual abuse, and neglect is extremely important, but newsletter articles, association meeting offerings, and encouraging the development of additional continuing education courses on the topic are best first steps. The American Society of Consulting Pharmacists successfully used this approach to address elder abuse. The Board would be happy to work with you on this issue as the 2014 Legislation Session approaches.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
III.Committee Reports A. Practice Committee	H. Finke, Chair	**Inquiries:** 1) Edward Winiecki, Consumer **Edward Winiecki** **Draft Bd Response - Meds from India** **The Board approved the following response:** Thank you for your letter to Governor Martin O'Malley concerning labeling prescription medications with the country of origin. The Governor asked me to respond on his behalf. The Board of Pharmacy shares your concern regarding prescription medications manufactured abroad, however; regardless of the location of the manufacturing plant, in order to be dispensed in the United States the FDA would have approved the medication and given it a NDC number. The FDA applies the same quality standards whether a prescription medication is manufactured in the United States or another country. So that the FDA may be made aware of your concerns, please go to the link below to report your concerns. https://www.accessdata.fda.gov/scripts/medwatch/ 2) Dr, Geoff Coleman, Montgomery Hospice/Palliative Medicine Consultants **Nurses dispensing OTC to hospice patients** **Draft Bd Response - OTC meds delivered to hospice** **The Board approved the following response:** Thank you for contacting the Maryland Board of Pharmacy concerning whether it is permissible for a nurse to carry OTC medications to a patient's house. Would it have to be labeled by a pharmacy or could it come out of a larger stockpile of medications on hand?	Approved. Approved.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		Any individual may transport OTC medications, so long as those medications have the required labeling. Labeling is a pharmacy function. Medications may come from a larger stockpile, but would have to be properly labeled by a pharmacy. You may want to refer to the Office of Health Care Quality (OHCQ) that regulates hospices and also the Maryland Board of Nursing that regulates nurses. A contact at OHCQ is Joyce Janssen (410) 402-8140 or joyce.janssen@maryland.gov . A contact at the Board of Nursing is Shirley Devaris (410) 585-1902 or Shirley.devaris@maryland.gov 3) John Beckman, Beckman's Green Street Pharmacy **Beckman's Pharmacy DTM question** **Draft Bd Response – DTM** **The Board approved the following response with an additional sentence indicating that pharmacists do not have prescriptive authority.** Thank you for contacting the Maryland Board of Pharmacy concerning whether pharmacists are allowed to sign prescriptions intended to be filled at community pharmacies when participating in drug therapy management in a hospital setting. Pharmacists do not have prescriptive authority in Maryland and may not sign prescriptions. Prescriptions received at a community pharmacy have to be signed by a health care professional with prescriptive authority.	Approved.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		4) Roman Kaplan **Sabbath dispensing - not on orig agenda** **Draft Bd Response - Sabbath Dispensing** **The Board approved the following response with a revision to the first answer:** Thank you for contacting the Maryland Board of Pharmacy concerning dispensing medications under different scenarios during the Sabbath. Below you will find responses to your inquiries: *1) MD writes a script for certain medications (no controlled substances) for OFFICE USE, which then are stored at someone's home (not MD's, not RPh's) or synagogue office, and are available in emergent medical situations on Sabbath to be dispensed by an MD to a patient.* *a. Medications are bought with cash from the pharmacy, insurance (3rd parties) not involved* If rabbi happens to be a physician, then this situation would be acceptable only if the prescription was written for a specific patient, otherwise it would not be allowed under Maryland law. Physicians may not write a prescription for office use. *2) Same scenario as #1, except, an RPh is involved, such the meds are stored at an RPh's home and are dispensed to a patient by an RPh from his home per verbal from MD* This would not be allowed. A pharmacist may not store prescription medications in the pharmacist's home. Prescription medications are not allowed to be stored at a "depot." A "depot" is defined as a location where filled prescriptions are stored before delivery to the intended patient or the intended patient's authorized agent. COMAR 10.34.25.02 and .04 *3) A contract is made with a local pharmacy, where certain meds are stored*	Approved as revised.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		at someone's home (not MD's, not RPh's) or synagogue office, and are available in emergent medical situations on Sabbath to be dispensed by an MD to a patient. After Sabbath MD writes a script and it is processed at the contracted PHARMACY, via 3rd party, if applicable (retroactively). Prescription medications are not allowed to be stored at a "depot." A "depot" is defined as a location where filled prescriptions are stored before delivery to the intended patient or the intended patient's authorized agent. COMAR 10.34.25.02 and .04 *4) Same scenario as #3, except, an RPh is involved, such the meds are stored at an RPh's home and are dispensed to a patient by an RPh from his home per verbal from MD, and then after Sabbath MD writes a script and it is processed at the contracted PHARMACY, via 3rd party, if applicable (retroactively).* This would not be allowed under Maryland law. A pharmacist may not store prescription medications in the pharmacist's home. Prescription medications are not allowed to be stored at a "depot." A "depot" is defined as a location where filled prescriptions are stored before delivery to the intended patient or the intended patient's authorized agent. COMAR 10.34.25.02 and .04 The Board appreciates it that you have made your inquiries to the Board. The Board encourages you to develop appropriate procedures for emergent care on the Sabbath. **5) John Sullivan, Managing Partner, Marjo, LLC - NIH Grant proposal** **Specific Aims 10-16-2013** **Draft Bd Response - NIH grant concept** **The Board approved the following response with the deletion of the sentence regarding risk to a pharmacist:** The Maryland Board of Pharmacy has received your inquiry from the Maryland Board of Physicians requesting that the Board of Pharmacy review the information submitted in regards to the Opiate Dispenser Program grant proposal you plan on submitting to the National Institute of Health.	Approved as revised.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		After reviewing the proposal for the Opiate Dispensing Program the Board has decided to not provide any comments in support of this program. Although the Board commends you for working towards reducing the amount of prescription drug abuse in teens the proposal does not seem logistically feasible. According to the proposal pharmacists will be asked to dispense a locked box which contains medications when the pharmacists have not personally performed a final check, as required by law. Thank you for seeking comment from the Maryland Board of Pharmacy.		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
B. Licensing Committee	L. Bradley-Baker, Chair,	**1. Review of Pharmacist Applications:** **A. Michelle Lee** - Pharmacist would like an extension of application to take the MPJE. Licensing Committee recommendation is to approve the extension until December 31, 2013 due to family medical issues.. **B. Olusevi Ogunvankin** - Pharmacist requesting waiver of reinstatement fees. Licensing Committee recommendation is to deny the request and to ,inform pharmacist that he has to pay the fees before he can be reinstated. **C. Robert Dunn** - Pharmacist requesting waiver of oral competency requirement because he stated there is no Berlitz office within 300 miles of his home and Berlitz has failed to get back in touch with him regarding his request to take examination online. Licensing Committee recommendation is to deny the request and to inform the pharmacist that he has to take the oral competency examination as well as pay reactivation fees as his application has now expired.	1A. Motion by Licensing Committee to approve request of Michelle Lee for an extension of time to take the MPJE until December n31, 2013.Motion was seconded by J. Smith. 1B. Motion by Licensing Committee to deny request of Olusevi Ogunvankin for a waiver of reinstatement fees and to inform him he must pay the fees before he can be reinstated.. Motion was seconded by C. Rochester. 1C. Motion by Licensing Committee to deny request of Robert Dunn to waive requirement of oral competency examination. Licensing Committee also moves to inform Robert Dunn that he has to take the oral examination as	1A. Motion was approved. 1B. Motion was approved. 1C. Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
			well as pay reactivation fees as his application has now expired. Motion was seconded by J. Smith.	.
		2. Review of Pharmacy Technician Applications: None. **3. Review of Distributor Applications:** None. **4. Review of Pharmacy Applications:** None. **5. Review of Pharmacy Technicians Training Programs:** None **6. New Business:**		
		A. **Walmart and Sam's Club Openings** – Would like clarification on a couple of questions regarding the opening of new locations. Licensing Committee recommendation is to inform company that as long as they have obtained MD permit they are able to process valid prescriptions, citing appropriate regulations in the letter.	6.A. – Motion by :Licensing Committee to inform company that as long as they have obtained MD permit they are able to process valid prescriptions, citing appropriate regulations in the letter. Motion was seconded by M. Gavgani.	6.A. – Motion was approved.
		B. Rx Prep – Would like the Board to review their remediation program and to refer those who have failed the NAPLEX repeatedly to them. Licensing Committee recommendation is to inform Rx Prep that the Board does not endorse any programs.	6.B. Motion by Licensing Committee to inform Rx Prep that the Board does not endorse any programs. Motion was seconded by J. Smith.	6.B. – Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		C. Technician Training Program Clarification – Discussion of ASHP 2020 requirements that all technician training programs have an experiential component. MD law prohibits programs that are not Board approved to complete experiential hours in MD licensed pharmacies. Licensing Committee recommendation is to plan to change regulations to include that MD will accept ASHP accredited programs to complete experiential hours in a MD approved pharmacy to obtain national certification.	6.C. Technician Training Program was referred back to the Licensing Committee for further research and discussion.	
C. Public Relations Committee	L. Bradley-Baker, Chair	**Public Relations Committee Update:** • Outgoing Board Commissioner Recognition Event. , Commissioners Michael Souranis, Richard Matens, Rodney Taylor, Dave Chason and Stephanie Hammonds have left the Board within the last year. The Public Relations Committee is coordinating a recognition dinner after the Board's December public board meeting. • Script Your Future Baltimore Motivational Interviewing Session – L. Bradley-Baker reported that she and P. Gaither attended the Script Your Future Motivational Interviewing Session last week and that the session was very positive. The Public Relation Committee is considering a similar session for the Board's Continuing Education CE Breakfast next year. • Off-Site Board Meetings in 2014 – L. Bradley-Baker reported that Commissioner S. Roy has procured a location for the September 2014 public board meeting, the Western Maryland Health Center. The Public Relations Committee moved that the	Motion by the Public Relations Committee to change the date of the September, 2014 public board meeting from Wednesday, September	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		September 2014 public board meeting date be changed from Wednesday, September 17 to Friday, September 19, 2014 to accommodate all can attend.	17 to Friday, September 19, 2014. Motion was seconded by S. Roy	Motion was approved.
D. Disciplinary	M. Gavgani, Chair	**Disciplinary Committee Update** – • Community Inspections-PDMP – M. Gavgani reported that the Disciplinary Committee is updating the Inspection Form for Community Pharmacies to include a question that asks if the pharmacy is enrolled in the Prescription Drug Monitoring Program (PDMP) and requiring the pharmacy to submit verification, if they are exempt. • Fines to pharmacists and pharmacy technicians for failure to notify the Board about change of address. – Both the Licensing Unit and the Compliance Unit have been having difficulty with mail being returned because licensees' addresses changed. The Disciplinary Committee will begin enforcing the fine that is already established by regulation when the Board learns that a licensee's address or employer has changed and the Board was not notified.		
E. Emergency Preparedness Task Force	L. Bradley-Baker, Acting Chair	**Emergency Preparedness Task Force Update:** 1. DHMH feedback on EPTF's role during September 2013 drill - L. Bradley-Baker reported that the DHMH gave very high praise to the EP Task Force and Pharmacy Volunteers who participated in last month's state exercise. She quotedDHMH which said, "**The pharmacist volunteers demonstrated commitment to their role in support of RSS operations. The Just-in-Time training was valuable in fostering a sense of mission as well as developing a sense of engagement within the RSS ICS**		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		structure. In addition, the pharmacist volunteers performed numerous critical tasks without failure or challenge." Volunteers who participated in the drill were: Cynthia Anderson (former board commissioner); Simon Bae; Eric Barbye; James Bresette; Miesha Buckner; Phil Cogan; Veronica Hunt; Han Luu; John Chad Morris; Renee Riddix-Hilliard; Rosanna Powell; EP Task Force (EPTF) Members: Arnie Honkofsky; Larry Hogue; Bart Regan; Sajal Roy; Don Taylor; Hoai-An Truong; and Reid Zimmer. 2. Recruitment of Pharmacy Volunteers for Emergency Preparedness – L. Bradley Baler reported that the EPTF is working on several avenues to recruitment new pharmacist, pharmacy technicians and pharmacy student to become volunteers: -Direct follow-up with pharmacists and pharmacy technicians who indicate their interest to become a volunteer on their new or renewal applications; -Publishing an article about the drill and the need for volunteers in the next board newsletter; and - Continuing Education credits (board-approved, not ACPE) for EP drills and training: The Emergency Preparedness Task Force will submit training modules to the board's secretary for review for board approved continuing education credit. 3. Expanded scope of EPTF - DHMH's Office of Preparedness &Response (OP&R) is looking to expand its Emergency Medical Countermeasures Plan (formally known as the SNS) -The role of the EP task force will have to expand (i.e., in a natural disaster, such as a hurricane, how can the EP task force		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		and volunteers assist in distributing medications (especially chronic one)? -We need to consider developing distribution plans for things other than bioterrorism events -Board members should direct any ideas for this expanded role to Lynette Bradley-Baker ***There are emergency protocols that are available to pharmacists when the Governor of Maryland operates under a declared state of emergency---the board can be proactive in posting them on the emergency preparedness web page. 4. , L. Bradley-Baker, on behalf of the EPTF, congratulated Don Taylor, former board president and commissioner, who was named the chair of the subcommittee on RSS operations. This appointment is the first time that a pharmacist has been the chair of a committee or subcommittee within OP&R and is a testament to the hard work and dedication of Don and the EPTF.		
IV. Other Business & FYI	L. Israbian-Jamgochian, President	There was no other business presented.		
V. Adjournment	L. Israbian-Jamgochian, President	The Public Meeting was adjourned at 12:40 P.M. At 1:30 P.M. L. Israbian-Jamgochian convened a Closed Public Session to conduct a medical review of technician applications. C. The Closed Public Session was adjourned at 2:00 P.M. Immediately thereafter, L. Israbian-Jamgochian convened an Administrative Session for purposes of discussing confidential disciplinary cases. With the exception of cases requiring recusals, the Board members present at the	Motion by H. Finke to adjourn the Public Board meeting pursuant to State Government Article 10-508)a)(13) and (7) for the purpose of engaging in medical review committee review deliberation	Motion was approved.

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)	Results
		Public Meeting continued to participate in the Administrative Session.	regarding confidential matters in applications Meeting. The motion was seconded by C. Rochester.	

Attachment No. 1

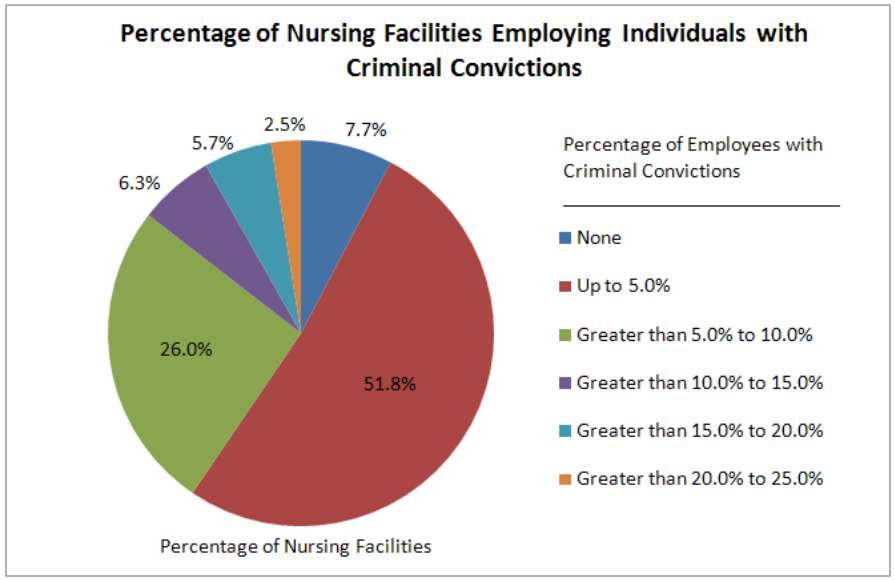
MARYLAND BACKGROUND CHECK PROGRAM

Lorena de Leon-Program Administrator-MBCP

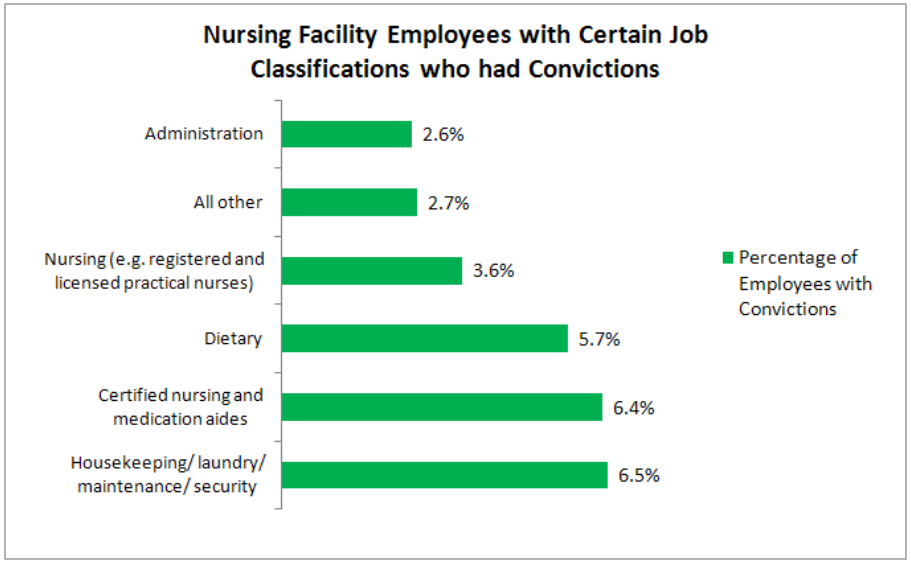
National Background Check Program Overview and Goals

- Created under the Patient Protection and Affordable Care Act of 2010
- Intended to help States protect vulnerable populations from abuse
- Managed by US Department of Health and Human Services (HHS) CMS
- Purpose of grant to identify efficient, effective, and economical procedures for States to conduct State and Federal background checks
- Establishes framework for standardized nationwide program for States to conduct fingerprint-based background checks on all prospective direct patient access employees

HHS OIG Report Findings – Convictions



HHS OIG Report Findings – Jobs



Common features of State programs

- Providers have web access to applicant information and status
- Applicants submit fingerprints once for multiple employment positions Depends on the State's rap back capabilities

- Providers released from liability
- Standard Determination Process Eligibility Rules applied to all applicant

- Three basic parts Application and Registry Checks
- Fingerprints and Criminal History
- Fitness Determination and Notification

Automated Registry Checks Features/Benefits

- Registries customized to each State, including
  - –Certified nursing assistant
  - –Professional licensing
  - –Abuse and offenders
- All required registries automatically presented State, federal, applicant former residence
- Employer can add registries for individual applicants
- For registries granting electronic access to data, ALL searching and matching is automatic; employer reviews and records results
- Registry findings report generated for employer and applicant use
- Automatic re-searching ("rap back") of OIG LEIE and other registries with electronic data connection

Maryland Background Check Program (cont.)

- "One stop shop"
- Provider will log on to MBCP system and run an auto query for preset registries
- The query will generate a "Hit" or "No Hit" status
- If a "Hit" status is found, applicant is automatically disqualified
- If a "No Hit" status is found, applicant is cleared for fingerprinting

Maryland Background Check Program (cont.)

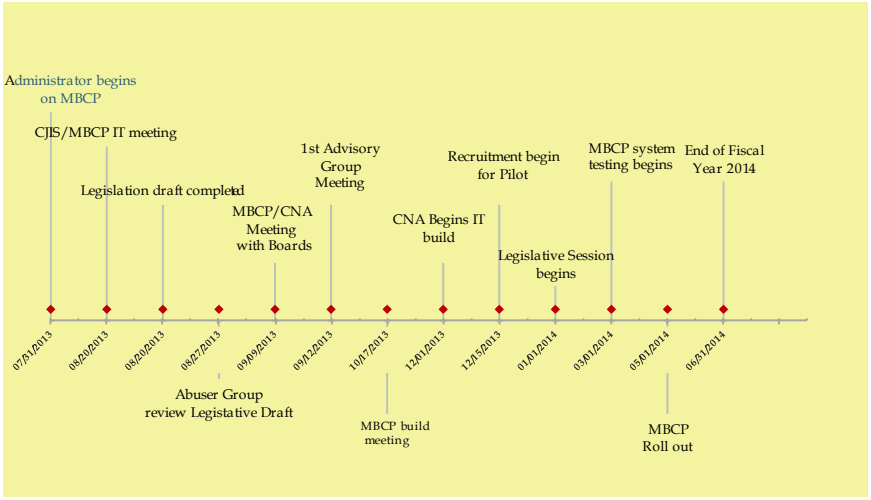
- Provider will send applicant to a LiveScan vendor for fingerprinting
- Result review by MBCP determination analyst for fitness determination
- Results are generally back to provider within 24 to 48 hours
- State currently has rapback system available via CJIS
- Federal rapback anticipated for Summer 2014

Maryland Background Check Program (cont.)

Process Improvements and safer care

- Savings in unnecessary fingerprinting by utilizing registry query system
- Faster processing time due to "one stop shop"
- Transfer of liability from provider to MBCP =potential cost reduction in liability insurance
- Follow up information with rapback system

Timeline


Administrator begins on MBCP
CJIS/MBCP IT meeting
Legislation draft completed
MBCP/CNA Meeting with Boards
1st Advisory Group Meeting
CNA Begins IT build
Recruitment begin for Pilot
Legislative Session begins
MBCP system testing begins
End of Fiscal Year 2014
07/01/2013
08/20/2013
08/20/2013
08/27/2013
09/09/2013
09/12/2013
10/17/2013
12/01/2013
12/15/2013
01/01/2014
03/01/2014
05/01/2014
06/31/2014
Abuser Group review Legistative Draft
MBCP build meeting
MBCP Roll out

Questions

Contact information:

Lorena de Leon
55 Wade Avenue
Catonsville, MD 21117
Phone 410-402-8181
Lorena.deLeon@Maryland.gov

Attachment No. 2.

RESOLUTION 1:
Pennsylvania presented a resolution to ban the sale of tobacco in registered pharmacies. After much discussion, with a vote of 6-1, the resolution did not move forward.
Delaware (seconded by Virginia) motioned to endorse the 1988 NABP position statement. The motion was carried unanimously.
District 2 Resolution – Pharmacies Selling Tobacco Products
Whereas, In the United States, tobacco use is responsible for nearly 1 in 5 deaths; this equals about 443,000 early deaths each year (Source: Cancer Facts & Figures 2013), and Whereas, state boards of pharmacy are charged with protecting the public health, safety and welfare as related to services provided by pharmacies and pharmacists; and Whereas, It is an inherent conflict of interest for pharmacies to dispense the medications that treat heart disease, lung disease, and cancer -- and then also sell tobacco, encouraging pharmacies to stop selling tobacco products and work toward a Smoke Free Society
Therefore be it Resolved, that the National Association of Boards of Pharmacy reaffirm its existing policy
encouraging pharmacies to stop selling tobacco products and work toward a Smoke Free Society.
Background:
NABP Resolution 88-06-92-
Therefore, Be It Resolved, that NABP encourage the pharmacy community to stop the selling of tobacco products in pharmacies and work toward a Smoke-Free Society by the Year 2000; and Be It Further Resolved, that NABP encourage state boards of pharmacy to support and promote programs that educate the public of the harmful effects of smoking; and Be It Further Resolved, that NABP encourage pharmacists to become non-smoking exemplars to the community in which they live, and that all workplaces of these pharmacists become Smoke-Free by the Year 2000; and Be It Further Resolved, that NABP urge the medical community, related groups, educational institutions,

and government agencies, at the federal and state level, to more effectively demonstrate the health hazards in the use of tobacco products and work toward promoting a Smoke-Free Society by the Year 2000.

RESOLUTION 2:
Presented by Virginia, seconded by West Virginia and endorsed with a unanimous (7-0) vote.
District 2 Resolution – Permitting Residents to Obtain Drugs from Sources outside the US
Whereas, Maine has enacted a law allowing residents to obtain prescription drugs from sources outside the United States, and Whereas, these drugs are not FDA-approved drugs and therefore, may not be safe and efficacious, and Whereas, pharmacies located within the United States must be licensed by their resident Board of Pharmacy and may only dispense FDA-approved drugs, and Whereas, NABP's research indicates 97 percent of the internet sites do not conform with federal and state laws, often dispensing counterfeit drugs, and Whereas, there is potential for imminent patient harm with no regulatory oversight from the United States and accountability, Therefore, be it resolved that NABP continue its efforts in educating state policy makers and the public in the danger of obtaining prescription drugs from sources outside of the United States without federal and state oversight.

RESOLUTION 3:
Motion made by Virginia, seconded by Pennsylvania and passed unanimously (7-0).
District 2 Resolution – Pharmacy Robberies and Thefts
Whereas, in recent years, there has been an increase in armed robberies and internal and external thefts of controlled substances in pharmacies, and Whereas, armed robberies have resulted in injury and death and continue to pose a significant threat to pharmacy personnel and the public through bodily harm and the illicit use of the stolen controlled substances, and Whereas, the risk of armed robberies and thefts will potentially continue due to the national epidemic of prescription drug abuse and current economic conditions, and Whereas, the Boards of Pharmacy are responsible for establishing minimum criteria for the control and safeguards against diversion of drugs and protecting public health and safety, Therefore, be it resolved that NABP establish a taskforce to review actions taken by member boards to thwart the loss of controlled substances by armed robberies and internal and external thefts of pharmacies and mitigate potential harm to pharmacy personnel and the public, and recommend amendments to the minimum security standards in the Model Act, if necessary.